

Certificate of Analysis

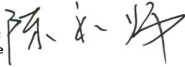
Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	Anti-CEA monoclonal antibody	Catalog Number	BENCEAS103
Date of Manufacture	Specific date	Lot Number	Specific lot number
Immunogen	N/A		
Species	Mouse	Expressed Host	N/A
Tag	N/A	Clone number	3E3
Isotype	IgG1	Molecular weight	150kDa
Product buffer solution	10mM PB+150mM NaCl+0.1% ProClin300,pH7.4	Preservative	ProClin300
Storage Conditions	-20±5°C, Avoid multiple freeze/thaw cycles	Date of Expiration	Shelf life:36 months
Applications	Detection	Platforms tested	ELISA、CLIA
Parameters tested on each lot			
Product appearance	Liquid		
Conc.determined by	UV absorption	Concentration /Recommended titer	Specific Concentration
Purification	Protein A chromatography	Purity	≥90%
Performance:			
Items	Passing criteria		Qualified or not
Immunoreactivity	At the same working concentration, the deviation of the activity in the test group from the control group is within ± 10%.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Clinical specificity	1. Internal negative control samples did not show any positivity during testing. 2. The slope was within range of 0.75-1.2 and R ² is not less than 0.85, when the results of the test group and in the 80 positive samples were compared.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Product stability	When accelerated stability testing at 37°C was performed, No change in specificity testing of the internal controls samples was observed and the change in activity was not higher than 20%.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Miscellaneous	N/A	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Remark	N/A		
Conclusion	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>		
Quality signature	N/A	Quality inspection date	N/A

管理者代表:
Management representative



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